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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,438	11/20/2001	William Stefan Bess	5724-03-EJF	3857

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EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/996,438		BESS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Dwayne C Jones		1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on the amendment of 08 APR 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,32,33,35-37,39-42 and 44-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,32,33,35-37,39-42 and 44-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 32-33, 35-37, 39-42, and 44-53 are pending.
2. Claims 1, 32-33, 35-37, 39-42, and 44-53 are rejected.

### ***Response to Arguments***

3. Applicants' arguments filed April 8, 2004 have been fully considered but they are not persuasive with respect to Nichols et al. of WO 97/37689 as well as Keown et al. of WO 95/11034. Applicants allege that neither of the prior art references of Keown et al. nor Nichols et al. teach the claimed embodiments of Applicants invention as instantly claimed in the amendment of April 8, 2004.

4. Applicants allege that Keown et al. do not disclose the claimed embodiments of Applicants invention. The following reasons dispute this argument. The instant claims are composition claims that require the presence of the acid salt of a sympathomimetic amine and an amino polymer. Keown et al. also teach of a pharmaceutical composition, which contains a sympathomimetic agent, such as ephedrine, (as cited from the abstract). In addition, Keown et al. also teach that this pharmaceutical composition contains various semi-permeable polymers that are known in the art such as those of, inter alia, U.S. Patent No. 3,546,142, (as cited on page 15 of Keown et al.). U.S. Patent No. 3,546,142 lists the amine-containing polymer of polydimethylaminoethyl methacrylate, (see column 2, lines 13-14). Accordingly, Keown et al. again render the instant composition claims obvious because the skilled artisan would have been

motivated to select a known material based on its suitability for its intended use, which supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In addition, composition claims are not deemed to be limited by an "intended use", see *In re Hack* 114 USPQ 161. Accordingly, the prior art reference of Keown et al. does render the instant invention obvious because Keown et al. teach of a sympathomimetic amine, namely ephedrine. Furthermore, applicants recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff*, *Comr. Pats.*, (DCCD 1982) 215 USPQ 310. Thus, the skilled artisan would have been motivated to use Keown et al. in order to arrive at the instantly claimed invention.

5. Applicants next allege that Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. also teach and provide explicit motivation to include other components such as "acrylic derivatives", (see page, lines 20-23). In view of this information, the skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of carriers and excipients and conventional ingredients that would render the instant invention obvious. Moreover, applicants recite the word "comprising", which

is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The rejection of claims 1, 32-33, 35-37, 39-42, and 44-53 under 35 U.S.C. 103 as being unpatentable over Keown et al. of WO 95/11034 is maintained for both the above-stated and reasons of record.

8. Claims 1, 32-33, 35-37, 39-42, and 44-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. of WO 97/37689. Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. do not specifically teach of an amino polymer. The skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of denaturants, especially when Nichols et al. teach of various denaturants, in particular amine-containing compounds and various types of polymer-containing compounds because the purpose of the denaturant is to make it

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difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds.

### ***Obviousness-type Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. The rejection of claims 1, 32-33, 35-37, 39-42, and 44-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. U.S. Patent No. 6,359,011 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to salts of transition metals whereas U.S. Patent No. U.S. Patent No. 6,359,011 is directed to transition metal salts of iron, copper, cobalt, manganese, nickel and zinc.

11. Claims 1, 32-33, 35-37, 39-42, and 44-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

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over claims 1-22, and 32-34 of copending Application No. 09/533,005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of a composition that contains inter alia, an amino polymer as well as a decongestant. In addition, Applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

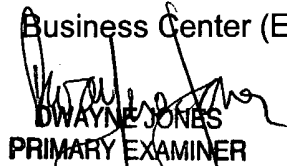
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584. The official fax No. for correspondence is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should

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you have any questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll free).

  
DWAYNE JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614

May 10, 2004